WO 99/03477 PCT/GB98/02110

## Claims

5

 A method for the treatment of diabetes mellitus and conditions associated with diabetes mellitus in a mammal, which method comprises administering an effective non-toxic and pharmaceutically acceptable amount of an insulin sensitiser, an insulin secretagogue and a biguanide antihyperglycaemic agent, to a mammal in need thereof.

- A method according to claim 1, wherein the insulin secretagogue is glibenclamide,
   glipizide, gliclazide, glimepiride, tolazamide, tolbutamide, acetohexamide,
   carbutamide, chlorpropamide, glibornuride, gliquidone, glisentide, glisolamide,
   glisoxepide, glyclopyamide, glycylamide or repaglinide.
- 3. A method according to claim 1, wherein the biguanide is metformin, buformin or phenformin.
  - 4. A method according to any one of claims 1 to 3, wherein the insulin sensitiser is 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound I).

20

- 5. A method according to any one of claims 1 to 4, which comprises the administration of 2 to 12 mg of Compound (I).
- 6. A method according to any one of claims 1 to 5, which comprises the administration of 2 to 4, 4 to 8 or 8 to 12 mg of Compound (I).
  - 7. A method according to any one of claims 1 to 6, which comprises the administration of 2 to 4mg of Compound (I).
- 30 8. A method according to any one of claims 1 to 6, which comprises the method the administration of 4 to 8mg of Compound (I).
  - 9. A method according to any one of claims 1 to 6, which comprises the administration of 8 to 12 mg of Compound (I).

35

10. A method according to any one of claims 1 to 6, which comprises the administration of 2 mg of Compound (I).

WO 99/03477 PCT/GB98/02110

11. A method according to any one of claims 1 to 6, which comprises the administration of 4 mg of Compound (I).

12. A method according to any one of claims 1 to 6, which comprises the administration of 8 mg of Compound (I).

5

30

- 13. A method according to claim 1, wherein the insulin sensitiser is (+) -5-[[4-[(3,4-dihydro-6-hydroxy-2, 5, 7, 8-tetramethyl-2H-1-benzopyran-2-yl)methoxy]phenyl]methyl]-2,4-thiazolidinedione (or troglitazone), 5-[4-[(1-methylcyclohexyl)methoxy]benzyl] thiazolidine-2,4-dione (or ciglitazone), 5-[4-[2-(5-ethylpyridin-2-yl)ethoxy]benzyl] thiazolidine-2,4-dione (or pioglitazone) or 5-[(2-benzyl-2,3-dihydrobenzopyran)-5-ylmethyl)thiazolidine-2,4-dione (or englitazone); or a pharmaceutically acceptable form thereof.
- 14. A pharmaceutical composition comprising an insulin sensitiser, an insulin secretagogue, a biguanide antihyperglycaemic agent and a pharmaceutically acceptable carrier therefor.
- 15. A composition according to claim 14, wherein the insulin secretagogue is asulphonylurea.
  - 16. A composition according to claim 14 or claim 15, wherein the insulin secretagogue is glibenclamide, glipizide, gliclazide, glimepiride, tolazamide or tolbutamide, acetohexamide, carbutamide, chlorpropamide, glibornuride, gliquidone, glicortide, glicological actions and action of the color of the col
- gliquidone, glisentide, glisolamide, glisoxepide, glyclopyamide, glycylamide or repaglinide.
  - 17. A composition according to claim 1, wherein the biguanide is metformin, buformin or phenformin.
  - 18. A composition according to any one of claims 14 to 17, wherein the insulin sensitiser is Compound (I)
- 19. A composition according to any one of claims 14 to 17, which comprises 2 to 12
  35 mg of Compound (I).

WO 99/03477 PCT/GB98/02110

20. A pharmaceutical composition comprising an insulin sensitiser an insulin secretagogue and a pharmaceutically acceptable carrier therefor, for use as an active therapeutic substance.

- 21. A pharmaceutical composition comprising an insulin sensitiser, an insulin secretagogue, a biguanide antihyperglycaemic agent and a pharmaceutically acceptable carrier therefor, for use in the treatment of diabetes mellitus and conditions associated with diabetes mellitus.
- 22. A composition according to any one of claims 14, 20 or 21, wherein the insulin sensitiser is (+) -5-[[4-[(3,4-dihydro-6-hydroxy-2, 5, 7, 8-tetramethyl-2H-1-benzopyran-2-yl)methoxy]phenyl]methyl]-2,4-thiazolidinedione (or troglitazone), 5-[4-[(1-methylcyclohexyl)methoxy]benzyl] thiazolidine-2,4-dione (or ciglitazone), 5-[4-[2-(5-ethylpyridin-2-yl)ethoxy]benzyl] thiazolidine-2,4-dione
   (or pioglitazone) or 5-[(2-benzyl-2,3-dihydrobenzopyran)-5-
- ylmethyl)thiazolidine-2,4-dione (or englitazone); or a pharmaceutically acceptable form thereof.